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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,551	10/17/2003	Indranil Nandi	G-33422P1/GPI	1169

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,551	NANDI ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the applicant's Oath or Declaration filed on 3/25/2004.

Receipt is also acknowledged of the applicant's Information Disclosure Statements filed on 7/19/2004 and 3/25/2004.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-13, drawn to a taste masking composition comprising micropellets, classified in class 424, subclass 489.

   II. Claim 14, drawn to a method of preparing a taste masking composition comprising micropellets via high-sheer granulation, classified in class 424, subclass 489.

   III. Claims 15-20, drawn to a method of preparing a taste masking composition comprising micropellets, classified in class 424, subclass 489.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and Invention II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case, the product can be made via a materially different method. The product can be made in the following manner:

(a) mixing at least one antibiotic, and optionally one or more excipients, to form a premix;

(b) adding a solvent, and optionally one or more excipients, to the premix formed in Step (a) and granulating in the presence of an impeller set at least at 50 rpm, to form a wet granulation;

(c) drying the wet granulation, and optionally milling and screening the dried granules to form micropellets; and

(d) coating the micropellets with at least one cellulose polymer; and

(e) coating the micropellets from Step (d) with at least one enteric coating polymer to form coated micropellets .

3. Inventions I and Invention III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made via a materially different method. The product can be made by high-sheer granulation.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions have distinct modes of operation. Invention II is concerned with the preparation of micropellets via high-sheer granulation whereas Invention III is drawn to producing micropellets by first mixing the chemical components and then drying the wet granulation.

5. Searching the inventions of Groups I – II together would impose a search burden on the examiner. In the instant case, the search of a composition and two distinct methods of preparing said composition would impose a search burden on the examiner.

6. Because these inventions are distinct for the reasons given above and the search required for each subset of Groups I – III are not required for one another, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with John Tallener on 6/9/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-20 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8, 12-13 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 5-6, 10-12, 16-17 of copending Application No. 10/768562 ('562). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Co-pending application '562 claims an antibiotic composition comprising (1) a core comprising an antibiotic, (2) an inner coating comprising a cellulose polymer which is not an enteric coating polymer, and (3) an outer coating comprising at least one enteric coating polymer (See claim 1 of '562). Like the instant application, '562 claims a composition having a particle size between about 100 microns to about 650 microns (See claim 1 of '562). The open "comprising" language in the instant application allows for additional limitations such as "a core comprising an antibiotic." In both the instant application and in co-pending application '562 the cellulose polymer can be

hydroxypropylmethyl cellulose and the enteric coating can be poly(methacrylic acid, ethyl acrylate) (See claims 6 and 12 of '562).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,221,402 ('402).

'402 disclose a taste-masking composition comprising a (1) core, (2) inner coating layer, and (3) outer coating layer (abstract). The core particles disclosed by '402 have an average particle diameter between 80 and 400 microns (column 3, lines 37-45). According to '402, antibiotics such as erythromycin may be used as an active agent in the composition (column 2, line 61 – column 3, line 12) and may be present in a range between 20-40% by weight (column 3, lines 46-58). The inner coating and core may comprise hydroxymethylpropyl cellulose (Tables 1(a), 1(b), 1(c) and column 6, lines 36-37). The outer cores, according to '402, may comprise Eudragit E100 (column 7, lines 1-11 and Tables 1(a), 1(b), 1(c)). The examiner notes that the instant claim set uses open "comprising" language. As a result, the instant claim set allows for additional limitations such as Eudragit NE30D in the inner coating layer. It should also be noted

that the mode of administration of the composition is considered to be a future intended use and, as such, is given no patentable weight.

The claims are therefore anticipated by US Patent 6,221,402 ('402).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,808,411 ('411) in view of US Patent 6,331,316 B1 ('316).

'411 teach microparticle compositions comprising an antibiotic, erythromycin coated with a cellulose-related polymer, such as hydroxypropylmethyl cellulose (abstract and Claims 1, 9-11). According to '411, the composition can be further coated

with a pH sensitive enteric coating such as Eudragit E-100 (column 5, lines 3-17). The antibiotic can constitute 25% to 95% of the composition (Claims 1 and 6). The composition can be prepared in the form of an oral administration composition (Claims 1, 10-11). According to '411, the microparticles can have a diameter of 297 microns or less (Claim 8 and column 4, lines 49-56).

'411 does not teach a microparticle composition comprising an outer coating further comprising poly(methacrylic acid, ethyl acrylate).

'316 teaches an enteric coated pharmaceutical tablet comprising an antibiotic, such as erythromycin (abstract and column 5, line 40). According to '316, it is advantageous to coat a tablet with an enteric substance, such as poly(methacrylic acid, ethyl acrylate), because the coating allows the tablet core to stay in tact when traveling through the stomach but selectively allows for dispersion of the active agent in the small intestine (column 4, lines 53-67). In other words, a tablet coated with poly(methacrylic acid, ethyl acrylate) allows the active agent to be selectively released in the small intestine as compared to the stomach. Because a tablet coated with an enteric substance, such as poly(methacrylic acid, ethyl acrylate), modulates the release of an active agent in the body, one of ordinary skill in the art would have been motivated to add a poly(methacrylic acid, ethyl acrylate) outer coating to the composition proposed by '411. Based on the teachings of '316, there is a reasonable expectation that an enteric poly(methacrylic acid, ethyl acrylate) outer coating would effectively modulate

whether a tablet comprising an active agent releases said active agent in the stomach or small intestine. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an enteric poly(methacrylic acid, ethyl acrylate) outer coating to the composition proposed by '411 in view of the teachings of '316.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588 . The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.

6/15/08

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500